

(v) The procedures which the IACUC will follow to fulfill the requirements set forth in this subpart;

(vi) The health program for personnel who work in laboratory animal facilities or have frequent contact with animals;

(vii) The gross square footage of each animal facility (including satellite facilities), the species housed therein and the average daily inventory, by species, of animals in each facility; and

(viii) Any other pertinent information requested by OPRR.

(2) *Institutional status.* Each institution must assure that its program and facilities are in one of the following categories:

(i) *Category 1—Accredited* by the American Association for the Accreditation of Laboratory Animal Care (AAALAC). All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by AAALAC, or another accrediting body recognized by PHS.²

(ii) *Category 2—Evaluated* by the Institution. All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once each year. The IACUC shall use the *Guide* as a basis for evaluating the institution's program and facilities.

A report of the IACUC evaluation shall be submitted to the institutional official and updated on an annual basis.³ The initial report shall be submitted to OPRR with the Assurance. Annual re-

ports of the IACUC evaluation shall be maintained by the institution and made available to OPRR upon request. The report must contain a description of the nature and extent of the institution's adherence to the *Guide* and this policy.⁴ The report must identify specifically any departures from provisions of the *Guide* and this policy, and state the reasons for each departure. If program or facility deficiencies are noted, the report must contain a reasonable and specific plan and schedule for correcting each deficiency. The report must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, in the judgment of the IACUC and the institutional official, is or may be a threat to the health or safety of the animals. Failure of the IACUC to conduct an annual evaluation and submit the required report to the institutional official may result in PHS withdrawal of its approval of the Assurance.

(3) *Institutional Animal Care and Use Committee (IACUC).* (i) Each institution shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through experience and expertise of its members, to oversee the institution's animal program, facilities and procedures.

(ii) The Assurance must include the names, position titles and credentials of the IACUC chairperson and the members. The committee shall consist of not less than five members, and shall include at least:

(A) One Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the institution;

(B) One practicing scientist experienced in research involving animals;

(C) One member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and

(D) One individual who is not affiliated with the institution in any way

care and use of animals in PHS-supported activities is appropriate and humane in accordance with this policy. However, each institution may identify the committee by whatever name it chooses. Membership and responsibilities of the IACUC are set forth in PHS 380.205(d).

²As of the issuance date of this policy the only accrediting body recognized by PHS is the American Association for Accreditation of Laboratory Animal Care (AAALAC).

³The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to conduct or assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.

⁴If some of the institution's facilities are accredited by AAALAC or other accrediting body recognized by PHS, the report should identify those facilities and need not contain any further information about evaluation of those facilities.